

REMARKS

The specification has been amended to reflect the 371 status.

In addition, the multiple dependencies of the claims have been removed, and new claim 6 has been added corresponding to new claim 6 presented during prosecution of the international application.

Attached to this amendment is a copy of a brief explanation about claim 6 which was submitted under Article 19 during prosecution of the international application.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "**Version with markings to show changes made**".

Favorable action on the merits is solicited.

Respectfully submitted,

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DESCRIPTION

EXTERNAL SKIN PATCH
Technical Field

This application is a 371 of PCT/JP00/07451 filed October 25, 2001.

The present invention relates to antiphlogistic
5 analgesic external preparations. In particular, it relates
to an external skin patch having greatly improved
antiphlogistic analgesic effects which has a drug reservoir
layer comprising a drug-containing base containing an
adhesive gel base which contains a water soluble polymeric
10 material, a crosslinking agent, water and a humectant as its
essential components, and a local anesthetic and a
nonsteroidal antiphlogistic analgesic agent as medicinal
components.

Background Art

15 At present, many kinds of nonsteroidal antiphlogistic
analgesic agents having excellent anti-inflammatory,
analgesic, and antipyretic actions, have been developed,
and widely used against rheumatic disease, a postoperative
pain or the pain after removal of a suture. Such a
20 nonsteroidal antiphlogistic analgesic agent has been
originally developed as an oral preparation, and has been
employed as a useful therapeutic agent, however, the oral
administration of such a nonsteroidal antiphlogistic
analgesic agent may cause adverse effects such as
25 gastrointestinal tract disorder etc.

CLAIMS

1. An external skin patch, comprising a substrate and a drug reservoir layer coated on the substrate, in which the drug reservoir layer comprises a drug-containing base
5 containing an adhesive gel base which contains a water soluble polymeric material, a crosslinking agent, water and a humectant as essential components, and a local anesthetic and a nonsteroidal antiphlogistic analgesic agent as medicinal components.

10 2. An external skin patch according to claim 1, in which the local anesthetic comprises one or more kinds of compounds selected from the group consisting of tetracaine, procaine, dibucaine, lidocaine, benzocaine, xylocaine, and pharmaceutically acceptable salts thereof.

✓ 15 3. ~~An external skin patch according to claim 1 or claim 2,~~ in which the nonsteroidal antiphlogistic analgesic agent comprises one or more kinds of compounds selected from the group consisting of indomethacin, ketoprofen, piroxicam, felbinac, bufexamac, suprofen, flurbiprofen, diclofenac,
20 ibuprofen and pharmaceutically acceptable salts thereof.

✓ 4. ~~An external skin patch according to any of claims 1 to 3,~~ in which the drug-containing base contains the local anesthetic in an amount of 0.1 - 50 % by weight.

✓ 5. ~~An external skin patch according to any of claims 1 to 4,~~ in which the drug-containing base contains the

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nonsteroidal antiphlogistic analgesic agent in an amount of
0.05 - 10 % by weight.

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